

**Before the
Federal Communications Commission
Washington, DC 20554**

In the Matter of

Amendment of Parts 2 and 95 of the
Commission's Rules To Establish The
Medical Data Service at 401-402 and 405-
406 MHz

RM No. 11271

REPLY COMMENTS OF MEDTRONIC, INC.

MEDTRONIC, INC.

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SUMMARY

The Medical Data Service (“MEDS”) Petition for Rulemaking received strong support from multiple sectors of the healthcare industry. The commenting parties recognize that the MEDS would improve the quality of medical care and substantially lower the cost of providing that care. The proposed medical data service would operate at 401-402 and 405-406 MHz sharing spectrum on a secondary non-interference basis with federal meteorological users.

Medical device manufacturers Transoma Medical and DePuy Orthopaedics would use the new service to develop advanced medical equipment and applications that take advantage of ultra-low-power wireless connectivity. Noted medical researcher, Dr. W.G. Scanlon highlights the advantages of using the MEDS to support body-area networks made up of patient-worn sensors, implanted medical devices, and external medical monitoring and control equipment. And, Zarlink Semiconductor is eager to develop transceiver chips for the MEDS.

The MEDS proposal would support the Bush Administration’s Health Information Technology agenda. President Bush has set forth a goal of assuring that most Americans have accessible electronic patient records by the year 2014. The MEDS, which would allow the automatic collection of patient data, would support that goal and also bring administrative efficiencies to hospitals and other medical facilities. Indeed, electronic medical records would provide medical professionals quick access to the potentially lifesaving information in many patients’ medical history file. Moreover, the MEDS would support remote monitoring applications to improve medical services to patients in rural and remote areas of the country.

Medtronic urges the Commission to move swiftly towards authorizing the MEDS as set forth in the Petition for Rulemaking.

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There is strong support for the proposed Medical Data Service ("MEDS") allocation at 401-402 and 405-406 MHz.¹ The commenting parties recognize the promise of a new medical service that will support short-range wireless medical connectivity among a broad range of body-worn sensors, implanted medical devices, and external monitoring and control equipment in hospital rooms, physicians' offices, assisted living facilities, and patient homes. Such advanced wireless connectivity will enhance patient quality of life, improve the level of medical care, and substantially lower healthcare costs. The FCC should promptly allocate the 401-402 and 405-406 MHz bands for the MEDS to enable the next generation of medical applications that make full use of wireless connectivity.

¹ Six out of the seven parties that filed opening comments supported the MEDS proposal. *See* Comments by Dr. W.G. Scanlon ("Dr. Scanlon Comments"); Comments of Medtronic Inc. ("Medtronic Comments"); Comments of Transoma Medical ("Transoma Comments"); Comments of Zarlink Semiconductor Inc. ("Zarlink Comments"); Sept. 23, 2005, RM No. 11271; Statement in Response to Petition For Rulemaking of DePuy Orthopaedics, Sept. 22, 2005, RM-11271 ("DePuy Orthopaedics Statement"); *see also* Comments of DexCom, Inc., Sept. 23, 2005 ("DexCom has no objection to a grant of additional spectrum for use by medical implant devices, ...").

The MEDS would be an ultra-low-power, private land mobile radio service in Part 95 of the Commission's rules that would share spectrum on a non-interference basis with primary federal users of the 401-406 MHz band, the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services (collectively "METAIDS"). Thus, the MEDS proposal is fully consistent with the express goals of the Memorandum of Understanding between the FCC and NTIA to "promote the efficient use of spectrum" through use of "spectrum management techniques to promote increased shared use of the spectrum that does not cause harmful interference."² Indeed, as President Bush has recognized: "We must unlock the economic value and entrepreneurial potential of U.S. spectrum assets while ensuring that sufficient spectrum is available to support critical Government functions."³ The MEDS Petition carries that goal forward.

I. THE MEDS PETITION RECEIVED STRONG SUPPORT FROM MULTIPLE MEDICAL DEVICE MANUFACTURERS, A WIRELESS TRANSCEIVER CHIP MAKER, AND A LEADING MEDICAL RESEARCHER.

The Petition for Rulemaking received strong support from several medical device manufacturers, an RF transceiver chipmaker, and a top medical researcher. These parties note the key role that the MEDS would play in improving the quality of medical care. They also agree that the MEDS would help address the rapidly rising cost of health care through advanced medical applications, such as body-area networks, and patient monitoring applications. Thus, the

² Memorandum of Understanding Between the FCC and the NTIA, Jan. 31, 2003. *See also* 47 U.S.C. § 157(a) ("It shall be the policy of the United States to encourage the provision of new technologies and services to the public.").

³ George W. Bush, Presidential Memo on Spectrum Policy, Memorandum for the Heads of Executive Departments and Agencies, Subject: Spectrum policy for the 21st Century, June 5, 2003, available at <http://www.whitehouse.gov/news/releases/2003/06/20030605-4.html> last accessed October 11, 2005.

new service would allow elderly and infirm individuals to live independently for longer periods of time via remote monitoring.

A. Transoma Medical Extols The Benefits of Remote Monitoring and DePuy Orthopaedics Is Exploring Groundbreaking Medical Applications.

Transoma Medical, the leading provider of implantable wireless vital sign monitors, urges the Commission to move swiftly towards authorizing the MEDS. This company develops innovative medical devices that monitor a patient's health while the patient goes about their daily activities, greatly enhancing the patient mobility and offering peace of mind to infirm individuals and their families. Transoma also explains that "[t]he information these devices provide will allow physicians to determine the status of the patient's condition at home in real time – providing for early detection of events that may threaten the patient's life or lead to hospitalization."⁴

Remote communication of patient medical data could allow a patient to skip a trip to the physician's office if the patient's conditions are normal, directly reducing healthcare costs and benefiting the economy. Such communications made possible via the MEDS also could allow physicians to consult with and treat patients remotely. This would have a significant impact on patients who live in remote and rural areas of the country. And, as Medtronic has explained, because physicians will have increased access to medical data from patients who are remotely monitored, patients likely will spend less time in doctors' offices when they do make the trip.⁵

⁴ See Transoma Comments. See also Zarlink Comments at 2.

⁵ See Petition for Rulemaking at 4-5.

DePuy Orthopaedics, a Johnson and Johnson company, also voiced support for the MEDS Petition for Rulemaking.⁶ This company is developing innovative medical devices and applications that could make use of the MEDS.

B. Dr. Scanlon Notes The Advantages of Using the New Service For Body-Area Networks.

Noted medical researcher, Dr. W.G. Scanlon, recognizes that “[t]here are many advantages and benefits associated with the use of wireless technology for medical applications of body area networks.”⁷ The expanded use of wireless implantable and body-worn MEDS devices for low-power body networks would offer patients more responsive and lower-cost therapy, protection from human error,⁸ improved quality of life and an enhanced level of care.

Physicians could use the new service to collect data from and control external and internal patient medical devices, such as blood glucose sensors, insulin pumps, neural stimulators, and chronic pain control devices.⁹ Body area networks that use the MEDS could be configured to perform therapeutic and diagnostic functions automatically.

⁶ See DePuy Orthopaedics Statement.

⁷ Dr. Scanlon Comments.

⁸ See Petition for Rulemaking at 3-5. Accuracy of medical data and prevention of human error is especially critical. See *In Hospital Deaths from Medical Errors at 195,000 per Year USA*, MEDICAL NEWS TODAY, Aug. 9, 2004.

⁹ See Chappell Brown, *Real-World Implants Are Arriving*, EE TIMES, Sept. 12, 2005, available at <http://www.eetimes.com/news/latest/showArticle.jhtml?articleID=170701430> last accessed Oct. 11, 2005 (“In the near term, electrodes that can be implanted and communicate with the nervous system are being used in products marketed by Medtronic Inc. (Minneapolis). Applications include controlling Parkinson’s tremors, alleviating pain and controlling heart rhythms to avoid attacks.”).

In addition, medical technologies heretofore unrealizable could be made possible via the MEDS. In the near future, “bio-chips will be used for cancer detection and assessing cardiac health, and will also be used in systems that monitor the coagulation of blood.”¹⁰ Diagnostic medical devices are being developed to help to make medicine more pro-active, helping to identify health issues before they become chronic problems.¹¹

As Dr. Scanlon understands, the 401-402 and 405-406 MHz bands are especially attractive for body area networks supported by coordinated communications among body-worn and implanted medical devices and external monitoring and control equipment.¹² Signals at 400 MHz propagate acceptably well through human tissue. RF transceivers communicating at 400 MHz can be designed with small antennas and allow for the transfer of a large amount of

¹⁰ Ciaran Buckley, *SFI Invests EUR16.5m In Bio-Chip Research*, ENN ELECTRICNEWS.NET, Sept. 7, 2005.

¹¹ *See id.*

¹² *See* Petition for Rulemaking at 13. The MEDS band is in a relatively low noise portion of the spectrum, as the only incumbent operations in the U.S. are the METAIDS users. U.S. allocation of the 401-402 and 405-406 MHz bands for the MEDS would encourage worldwide harmonization of a service band that the ITU-R has already found to be compatible with the incumbent users of the band. *See* Recommendation ITU-R SA.1346, Sharing Between The Meteorological Aids Service and Medical Implant Communications Systems (MICS) Operating in the Mobile Service In the Frequency Band 401-406 MHz (“ITU-R SA.1346”).

In addition to the U.S., the MEDS has been proposed in Europe and in Canada. International harmonization would serve the public interest by offering the international traveler with implanted or body-worn medical device technology an enhanced degree of freedom by ensuring that the traveler can receive appropriate medical attention at home and abroad. And, for the medical device manufacturers, international compatibility would allow development costs to be spread among multiple national markets. This would allow MEDS devices to be made available at lower cost.

data in a short timeframe.¹³ These characteristics are critical to patient networks comprised of body-worn and implanted medical devices, as these devices must be small and lightweight, and minimize battery drain to extend their useful life.¹⁴

C. Zarlink Semiconductor Is Ready To Develop Transceiver Chips That Operate In The MEDS.

Zarlink Semiconductor voiced strong support for the MEDS Petition for Rulemaking. Zarlink has designed one of the first medical implantable RF commercial grade transceiver chips used to link medical implants with external equipment using the Medical Implant Communications Service (“MICS”) band at 402-405 MHz.¹⁵ The Zarlink ZL70100 chip fully complies with the listen before transmit (“LBT”) and frequency agility requirements that the FCC established for the MICS band to enable successful spectrum sharing with METAIDS users and other MICS devices.

Zarlink would “welcome the opportunity to design a transceiver chip in compliance with the proposed Medical Data Service,” which, as Zarlink recognizes, is “based, in part, on the smart radio requirements developed for MICS.”¹⁶ Cambridge Consultants and AMI Semiconductor also have developed smart radio transceivers that comply with the FCC’s MICS

¹³ See, e.g., Amendment of Parts 2 and 95 of the Commission's Rules to Establish a Medical Implant Communications Service in the 402-405 MHz Band, *Report and Order*, 14 FCC Rcd. 21040, ¶¶ 6-8 (1999) (“*MICS Report and Order*”).

¹⁴ See ETSI TR 102 343 V1.1.1, Annex B, § B.2.3.

¹⁵ See Zarlink Comments.

¹⁶ See *id.* at 1-2.

rules.¹⁷ These companies' investment in MICS smart radio technology and the associated lessons learned will prove useful in the development of MEDS-compliant chips.¹⁸

II. THE MEDS, WHICH WOULD IMPROVE HEALTHCARE AND CONTRIBUTE TO \$77 BILLION IN MEDICAL HEALTHCARE SAVINGS, IS FULLY CONSISTENT WITH THE PRESIDENT'S HEALTH IT AGENDA.

Aside from the innovative MEDS applications that would improve the level of medical care to patients, the proposed service would lower considerably the huge administrative costs of providing medical care. The MEDS would provide for the use of wireless communications links to integrate patient medical data from body-worn and implanted devices to the electronic patient record.¹⁹ In addition to the remote monitoring applications described above, medical personnel would be able to retrieve data from patient devices upon arrival at the physician's office or hospital emergency room. These applications will limit errors and lower substantially the amount of paperwork and time spent recordkeeping and managing information in hospitals and physicians' offices today.

In fact, a very recent study by the RAND Corporation confirms that properly implemented Health Information Technology ("Health IT") would greatly lower costs and

¹⁷ See Petition for Rulemaking at 9-10.

¹⁸ See Zarlink Comments at 5.

¹⁹ See Milt Freudenheim, *Doctors Join to Promote Electronic Record Keeping*, N.Y. TIMES, Sept. 19, 2005 ("Electronic records, particularly ones that can be shared online by different doctors and hospitals, can improve the quality and safety of patient care by reducing errors that kill tens of thousands of patients each year."). This also will decrease the time that patients spend in the office and increase the level of care and amount of quality time with the attending physician.

significantly improve healthcare quality.²⁰ RAND estimates that annual savings from Health IT efficiency gains alone could amount to \$77 billion.²¹

Last year, to capitalize on the benefits of Health IT, President Bush set forth a plan to guide the nationwide implementation of Health IT in the private and public health care sectors. He set an ambitious goal of assuring that most Americans have electronic health records by 2014. As the President explained, “innovations in electronic medical records and the secure exchange of medical information will help transform health care in America – improving health care quality, reducing health care costs, preventing medical errors, improving administrative efficiencies, reducing paperwork, and increasing access to affordable health care.”²² Electronic files would give physicians access to potentially lifesaving information such as patients’ medical histories, lab test results, and the list of medications that have been prescribed.²³

Recently, Health and Human Services (“HHS”) Secretary Michael Leavitt appointed 17 members to the American Health Information Community, an organization charged with helping to meet President Bush’s goal of making available e-health records for every American.²⁴ This

²⁰ See RAND Corporation, *Health Information Technology: Can HIT Lower Costs and Improve Quality?* Sept. 2005, available at <http://www.rand.org/publications/RB/RB9136/> last accessed Oct. 11, 2005.

²¹ *Id.*

²² See *A New Generation of American Innovation*, Apr. 26, 2004 at 1, part of President Bush’s Technology Agenda: Promoting Innovation and Competitiveness, available at <http://www.whitehouse.gov/infocus/technology/> last accessed Oct. 11, 2005. In his 2004 State of the Union Address, President Bush stated: “By computerizing health records, we can avoid dangerous medical mistakes, reduce costs, and improve care.” *Id.* at 7.

²³ See Michael Fletcher, *President Promotes Switching To Electronic Medical Records*, USA TODAY, Jan. 28. 2005 at A7.

²⁴ See Danielle Belopotosky, *Health Tech Group Convenes First Meeting On E-Records*, NATIONAL JOURNAL’S TECHNOLOGY DAILY, Oct. 7, 2005. The members of the American Health (Continued)

HHS Health IT group, comprised of representatives from government agencies, the technology sector, patient advocate concerns, private employers, and insurance companies, is focusing in the short term on the immediate improvements that Health IT can achieve for consumers.²⁵

The MEDS would play a key role in realizing these important goals and substantial cost savings.

III. THE MEDS MUST SUPPORT RELIABLE MEDICAL COMMUNICATIONS AND SUCCESSFULLY SHARE SPECTRUM WITH OTHER USERS.

As Medtronic and others have explained, a spectrum access protocol implemented via smart radio technology is needed to enable reliable MEDS communications among multiple uncoordinated medical devices.²⁶ Justification of the need for interference reduction and avoidance mechanisms, such as smart radio technology, lies in the purpose of a medical data communications link that must share successfully limited spectrum resources among various uncoordinated and co-located medical devices.

A. The Nature Of MEDS Communications Necessitates Use of a Spectrum Management Approach That Is Self-Regulating and Can Support Various Uncoordinated Uses.

The nature of MEDS communications calls for implementation of a self-regulating spectrum management technique that avoids interference, provides for fast channel access in unused spectrum, and allows multiple uncoordinated medical devices to successfully share spectrum. Indeed, in environments where there is high concentration of patients in close

Information Community will meet regularly in Washington, D.C., and hold workshops and forums around the country. Members will lead working groups in a number of priority areas, including consumer-related benefits, improved delivery of health care and public health. *See id.*

²⁵ *Id.*

²⁶ *See* Petition for Rulemaking at 11, 14-16.

quarters, such as hospitals, nursing homes, and assisted living environments, such spectrum management techniques are a necessary means to ensure beneficial use of the spectrum well into the future.

MEDS operations would share spectrum on a non-interference basis with primary users of the 401-402 and 405-406 MHz band – METAIDS users. As a secondary user, MEDS must accept any interference that these primary users and other secondary users introduce. In fact, the spectrum environment at 400 MHz not only includes METAIDS users, but also noise sources that are particularly acute in medical environments.²⁷

Unlike other wireless operations on an unlicensed or non-exclusive licensing basis where failure of the communications link due to any reason (interference or excessive ambient signal levels) can be overcome by continued retry until successful, a spectrum access protocol for medical communications is needed to provide the maximum possibility for successful data transfer on the first try, thereby minimizing the impact on battery resources. Medtronic proposed the MEDS as a separate medical communications service to support applications that are less time sensitive and could accept interference or signal blockage without affecting the health or safety of the patient.

The key to Medtronic's proposal is a two-tiered spectrum access structure that would enable successful spectrum sharing among such medical devices.²⁸ First, devices that operate with transmit power of up to 25 microwatts EIRP would need to implement smart radio technology and follow the spectrum access criteria in Section 95.628(a), *i.e.*, the access criteria successfully being implemented in the adjacent MICS band. Thus, devices that make intensive

²⁷ See, e.g., ITU-R SA.1346.

²⁸ See Petition for Rulemaking at 11, Appendix A (proposed FCC Rule Section 95.628).

use of the spectrum or find increased reliability desirable would use smart radio technology to avoid interference from and to METAIDS devices and other MEDS devices.

Second, devices that operate with lower power, *i.e.*, 250 nanowatts EIRP, and with a duty cycle no greater than 0.1 percent, *i.e.*, no greater than 3.6 seconds of total transmission time in a one hour period (that is low-power, low-duty-cycle “LPLDC” devices) could transmit at will so long as the duty cycle limit is not exceeded. These LPLDC devices would support medical monitoring functions where patient safety is not impacted if the delivery of information is delayed.

In this way, the MEDS makes possible a broad range of body-worn and implanted device applications.

B. DexCom Supports the MEDS Allocation With Some Reservations.

DexCom supports the MEDS allocation with some reservations.²⁹ The company has developed two blood glucose sensors that operate just outside of the proposed MEDS band at 402.142 MHz – a Short Term Sensor (“STS”) that uses an implanted sensor and a body-worn transmitter and a Long Term Sensor (“LTS”) where the sensor and transmitter are both implanted. DexCom appears to be willing to move its operations to the MEDS bands but claims that its non-LBT devices require a 25 microwatt EIRP transmit power level.³⁰ At this time, however, DexCom has not substantiated its claimed need for this power level, and it is especially puzzling in view of other communication systems that operate over similar distances with significantly less power. Notwithstanding, the MEDS would support the higher power levels

²⁹ See DexCom Comments.

³⁰ See *id* at 3.

that DexCom claims to need, so long as DexCom's devices support LBT and frequency agility to avoid interfering with other users of the band.

C. Biotronik Claims That the MEDS Is Unwarranted And Opposes Allocation of Additional Spectrum for Medical Implants.

Biotronik opposes the MEDS allocation, claiming that the proposed service is unwarranted. According to Biotronik, the additional spectrum at 401-402 and 405-406 MHz is not needed for medical implants since there have been no interference reports from medical operations at 402-405 MHz.³¹

The MEDS proposal, however, is not limited to medical implants. The Petition for Rulemaking proposes a new service that would support a broad range of ultra-low-power medical applications outside of the MICS band. The MEDS, for example, would enable body-area networks supported by patient-worn sensors, implanted medical devices, and external monitoring and control equipment. As outlined above and as detailed in the Petition, MEDS applications include blood glucose sensors and insulin pumps to treat diabetes, neural stimulators, and chronic pain control devices. In addition, the MEDS would enable electronic collection of patient data from a broad range of medical sensors in support of the Bush administration's Health IT agenda.

³¹ Biotronik's claim that additional spectrum is not needed because "there have been no interference reports" fails to recognize the anticipated proliferation of medical devices in the Medical Implant Communications Service ("MICS") band for a wide variety of diagnostic and therapeutic applications, as well as totally new medical applications (*e.g.*, body-area networks) envisioned for the MEDS band.

In addition, Biotronik mistakenly interprets the MEDS Petition as proposing changes to the MICS. *See generally* Biotronik Comments. The MEDS proposal did not propose any changes to the MICS regulations.

D. The MEDS Protocol, Which Is Technology Neutral and Fosters Equal Sharing, Will Successfully Support The Communications Needs of Medical Devices Well Into The Future.

The access protocol proposed for the MEDS, which is based in part on the MICS protocol, is technology neutral and fosters equal sharing. It employs a threshold level to avoid other users of the spectrum, imposes a minimal listen time requirement before accessing spectrum, and fosters frequency reuse by requiring devices to cease transmission if no data is being transferred.

The communications needs of advanced medical devices will expand greatly in the coming years. Therefore, it is incumbent on the Commission to ensure that a broad range of medical applications and technologies can share the available spectrum without concern for interference blocking or corrupted data. This will keep the focus of the MEDS squarely on patient care, where it should be.

IV. CONCLUSION

Medtronic applauds the FCC for taking the first step towards authorization of the Medical Data Service at 401-402 and 405-406 MHz and urges the Commission to move swiftly towards promulgating the regulations set forth in the Petition for Rulemaking. The MEDS, which would allow ultra-low-power medical communications in a band that will continue to support critical government functions, would offer millions of Americans improved medical care at substantially lower cost.

Respectfully submitted,

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